The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
99 Chauncy Street, Boston, MA 02111

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

MONICA BHAREL, MD, MPH
Commissioner

Tel: 617-624-6000
www.mass.gov/dph

Circular Letter: DHCQ 17-4-671

TO: Chief Executive Officers, Acute Care Hospitals

FROM: Eric Sheehan, JD
Director, Bureau of Health Care Safety and Quality

DATE: April 7, 2017

RE: Regulatory and Policy Updates for Invasive Cardiovascular Services

The purpose of this Circular Letter is to inform you of updated regulations and policies related to the approval of hospital-based invasive cardiovascular services on hospital licenses by the Department of Public Health (DPH or the Department) pursuant to 105 CMR 130.900-.980. Neither cardiac catheterization nor electrophysiology procedures shall be performed in a satellite facility or a freestanding clinic. *See 105 CMR 130.900*

This circular letter provides guidance for the approval and continuing operation of cardiac catheterization services, including diagnostic, diagnostic and interventional, and pediatric cardiac catheterization services, other than cardiac surgery, as well as electrophysiology services, and shall supersede all prior guidance related to these services, including, but not limited to:

- DHCQ 14-12-624: Revised Primary PCI Guidelines, 12/12/14
- DHCQ 14-6-617: Policy Updates for Cardiac Catheterization Services, 7/14/14, including
  - Memo on Cardiac Catheterization (suspension of DHCQ 14-6-617), 1/20/15
  - Updated Memorandum on Cardiac Catheterization (revoking 1/20/15 memo), 4/28/15
- DHCQ 06-8-465: The MASS COMM Trial: Protocol, Community Hospital Eligibility, and Application Process for Participation in the Randomized Trial to Compare Safety and Long Term Outcomes for Percutaneous Coronary Intervention between Massachusetts Hospitals with Cardiac Surgery-on-Site and Community Hospitals without Cardiac Surgery-on-Site, 8/21/06
- DHCQ 02-06-426: Information Reporting Requirements for Cardiac Surgery and Angioplasty, 6/5/02
- DHCQ 02-01-421: Information Reporting Requirements for Cardiac Surgery and Angioplasty, 1/4/02
- DHCQ 6-00-405: Special Project to Allow Hospitals with Cardiac Catheterization Services but Without Cardiac Surgery Services to Provide Primary Angioplasty in the Treatment of Acute Myocardial Infarction, 6/15/00

Several issues will be addressed in this document, including:

I. Application Process;
II. Minimum Workload Requirements;
III. Cardiac Catheterization Services without Cardiac Surgery Services;
IV. Patient Outcome Data Requirements (Cardiac Surgery and PCI); and
V. Patient Selection and Exclusion Policies and Procedures

I. Application Process

Regulation of cardiac catheterization and electrophysiology has been based largely on sub-regulatory guidance, with approval for many services issued as special project waivers or through participation in trials. The amended hospital regulation provides a standardized application process and oversight framework that allows hospitals to seek approval to include these services on their licenses.

Each hospital seeking approval to provide adult cardiac catheterization services, pediatric cardiac catheterization services, and/or electrophysiology services, including hospitals that currently operate these services through a special project, waiver, or otherwise, shall submit an application (See Appendix A) for review by the Department which demonstrates hospital adherence to the standards and requirements in 105 CMR 130.900-980, as applicable, and all corresponding Department guidelines.

- Hospitals with existing invasive cardiovascular services must submit this form no later than October 2, 2017.

- Hospitals may apply for a new invasive cardiovascular service at any time, and may be subject to architectural plan review, determination of need, or both.

A hospital must address each requirement listed on the application with a "yes" or "no" answer. A hospital that does not meet a particular requirement will be required to submit accompanying documentation indicating how the hospital plans to achieve compliance, subject to review and approval by the Department.

II. Minimum Workload Requirements

Volume minimums, as established in regulation, provide limited application of a single quality measure, without allowing flexibility for the consideration of evolving standards and methodologies. By including these and other consensus measures in sub-regulatory guidance, based on accepted national standards, the Department will be better able to adjust and conform to practical quality measurement.

Each approved cardiac catheterization or electrophysiology service shall maintain a minimum annual caseload volume in accordance with guidelines set forth in Appendix B, based on guidelines and standards issued by American College of Cardiology, American Heart Association, Society for Cardiac Angiography and Interventions, and Heart Rhythm Society.

As part of the application for approval, a new service must demonstrate how it plans to reach and maintain the designated service volume minimum. Approval of the application shall be subject to DPH approval of the plan.

New services shall reach the minimum specified number of procedures within 24 months of approval of the service. Each new service shall submit Quality Assessment and Performance Improvement (QAPI) quarterly reports required under 105 CMR 130.965(E) including service volume during this initial 24-month period according to procedures outlined in Appendix B.

Any cardiac catheterization or electrophysiology service providing fewer than the specified number of procedures per year must submit to the Department a copy of the previous year's Quality Assessment and Performance Improvement (QAPI) quarterly reports required under 105 CMR 130.965(E), within 30 days of the end of the Department's fiscal year reporting period and quarterly thereafter, until the Department notifies the hospital to discontinue submission of the reports.

The QAPI quarterly reports must address the program components described in 105 CMR 130.965(C) as well as any other areas identified by the service or in the policies and procedures of the hospital as requiring attention. If the cardiac catheterization service does not have cardiac surgery services within the hospital, then the QAPI quarterly reports must also include the collaboration agreement requirements described in 105 CMR 130.975.

In addition to the QAPI reports, the hospital may be required to request a review of the catheterization or electrophysiology service by an appropriately qualified professional peer review organization or individual(s) approved by the Department, and submit the results of such review to the Department within 10 days of receipt. A physician conducting the peer review must certify that he or she has no conflict of interest regarding the hospital and physicians to be reviewed.

Based on a review of the QAPI reports and, if applicable, the results of the peer review, the Department will determine whether continued approval is warranted and any appropriate conditions that should apply.

III. Cardiac Catheterization Services without Cardiac Surgery Services

Clinical trials, including C-PORT and MassCOMM and experiences from other states have demonstrated that hospitals are able to deliver quality, safe cardiac catheterization services without cardiac surgery onsite. The Department has amended the regulation to reflect this progress.

While the amended regulation allows approval of cardiac catheterization services in hospitals without cardiac surgery services, such a hospital must maintain a current written collaboration agreement with at least one tertiary hospital with cardiac surgery services that complies with 105 CMR 130.975 and each provision listed on the application for approval. In addition, a hospital that is not approved to perform cardiac surgery must develop policies and procedures based upon the National Guidelines in American College of Cardiology/American Heart Association and Heart Rhythm Society, regarding appropriate procedure selection and exclusion.

Pursuant to 105 CMR 130.975, hospitals with no cardiac surgery on site may not perform the following procedures:

- Percutaneous balloon valvuloplasty;
- Myocardial biopsy; or
- Placement of any permanent intracardiac devices other than cardiac pacemakers, defibrillators or implantable event monitors.

Hospitals must be approved to provide cardiac catheterization services as a condition to approval to perform electrophysiology procedures, with the exception of implanting pacemakers, defibrillators and monitoring devices.

IV. Patient Outcome Data Requirements

To ensure the quality and safety of cardiac catheterization and electrophysiology services, the Department will continue to collect outcomes data based on accepted national standards and consensus documents. Through flexible sub-regulatory guidance and contract language, hospitals will be required to submit data that is responsive to evolving standards.

A. Cardiac Surgery

In accordance with 105 CMR 130.1203, the following guidelines apply to the submission of patient-specific data to the commonwealth's Data Analysis Center (DAC) vendor, MassDAC, by each hospital that provides cardiac surgery services, for each cardiac surgery performed. This data, which is subject to random audit by the Department, must be submitted in a manner defined by the Department, using Society of Thoracic Surgeons (STS) National Database Standards, as follows:

1. Enroll in the STS National Database;
2. Submit STS's designated adult cardiac component for each cardiac surgery performed following the STS harvest schedule
    a) directly to STS; and
    b) by uploading data via secure server to MassDAC.

B. Interventional Cardiac Catheterization

In accordance with 105 CMR 130.1303, the following guidelines apply to the submission of patient-specific data to the National Database of the American College of Cardiology (NCDR) and to the DAC by each hospital that provides interventional cardiac catheterization services, for each such procedure performed. This data, which is subject to random audit by the Department, must be submitted in a manner defined by the Department, using NCDR standards, and in accordance with requirements set forth by the Department as follows:

1. Enroll in the NCDR Cath PCI Database;
2. For each percutaneous coronary intervention performed, submit data, following the NCDR harvest schedule,
    a) to the ACC NCDR Cath PCI registry; and
    b) to MassDAC.

V. Patient Selection and Exclusion Policies and Procedures

Selection and exclusion criteria ensure that appropriate patients receive appropriate care based on appropriate considerations of acuity, invasiveness, and surgical support.

Each hospital must develop policies and procedures for patient selection and exclusion criteria based on nationally accepted published guidelines of the American College of Cardiology/American Heart Association and the Heart Rhythm Society. In accordance with 105 CMR 130.940(B), it is the responsibility of the physician director of the cardiac catheterization service to develop and implement these policies and procedures.

Questions about this letter should be directed to DPH.BHCSQ@MassMail.State.MA.US.